HEAT BIOLOGICS, INC.
Form 8-K
February 28, 2019

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (date of earliest event reported): **February 28, 2019**

Heat Biologics, Inc.

(Exact name of registrant as specified in charter)

Delaware

(State or other jurisdiction of incorporation)

001-35994	**26-2844103**
(Commission File Number)	*(IRS Employer Identification No.)*

801 Capitola Drive

Durham, NC 27713

(Address of principal executive offices and zip code)

(919) 240-7133

(Registrant s telephone number including area code)

N/A

(Former Name and Former Address)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of registrant under any of the following provisions:

- ¨ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ¨ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- ¨ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ¨ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ¨

If an emerging growth company, indicate by checkmark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ¨

Item 8.01. Other Events.

On February 28, 2019, Heat Biologics, Inc. (the "Company") issued a press release announcing updated interim results from its ongoing Phase 2 study investigating HS-110 in combination with Bristol-Myers Squibb s anti-PD-1 checkpoint inhibitor, nivolumab (Opdivo®), in patients with advanced non-small cell lung cancer (NSCLC) that were presented today at the ASCO-SITC Clinical Immuno-Oncology Symposium by Daniel Morgensztern, M.D., Associate Professor of Medicine and Director of Thoracic Oncology, Washington University School of Medicine, and Lead Investigator in the trial. Data were presented on both Cohort A and Cohort B of the trial. Cohort A enrolls only previously treated patients who have never received a checkpoint inhibitor (CPI), while Cohort B enrolls patients who received a minimum of 4 months of treatment with a CPI as part of their prior therapy, but subsequently had documented progressive disease. Preliminary data suggest that the addition of HS-110 to Nivolumab may restore responsiveness to treatment after tumor progression on prior checkpoint inhibitor. Improved survival was observed in patients with low CD8+ cold tumor at baseline compared to high CD8+ patients and the occurrence of injection site reactions correlated with improved overall survival.

Highlights for both cohorts are presented below:

Cohort B (patients who progressed after prior treatment with a checkpoint inhibitor)

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Of first 20 patients enrolled in this cohort:

o

Partial response (PR) in 3 patients (15%) per RECIST 1.1 and 4 patients (20%) per investigator assessment

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Stable disease (SD) in 8 patients (40%)

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Disease control rate (DCR) of 55%

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The 3 RECIST 1.1 PR patients had documented progression on a CPI immediately preceding study entry.

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Median progression free survival (mPFS) was 2.7 months (95% CI; 1.8 - 4.0 months).

Cohort A (patients who have never received a CPI prior to study entry)

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Of 42 patients enrolled by the cutoff date:

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PR in 9 patients (21%) per RECIST 1.1

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SD in 12 patients (29%)

o

DCR of 50%

o

Median overall survival not yet reached (60% still alive with a median follow-up of 14.4 months)

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Responses and disease stabilization are durable and long-lasting.

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Subgroup analyses, predefined in the clinical protocol, were performed for levels of tumor-infiltrating lymphocytes (CD8+ TILs) present in tumors at baseline. There was evidence of a survival benefit (HR = 0.39) in patients with levels CD8+ TIL ≤10% (i.e. “cold” tumors), a population that typically responds poorly to checkpoint inhibitors. The treatment benefit appeared to be independent of PD-L1 status (HR = 0.85).

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Immune reactivity to HS-110 was measured via ELISPOT assay (high vs. low compared to median) on patient peripheral blood mononuclear cells obtained before and during treatment with a median overall survival benefit of 6.2 months in the high ELISPOT group.

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Overall survival was significantly higher in patients that experienced at least one dermal injection site reaction to HS-110 at any time during study treatment, supporting HS-110’s mechanism of action (HR= 0.15 [95% CI: 0.05-0.45],

p=0.0001).

For both cohorts, treatment with HS-110 in combination with nivolumab was well tolerated, with no additional toxicities beyond those observed with single agent CPI therapy.

A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

A copy of the Company's revised corporate presentation that includes the interim results set forth above is attached as Exhibit 99.2 hereto, which is incorporated herein by reference.

The slide presentation attached as Exhibit 99.2 to this Report includes "safe harbor" language pursuant to the Private Securities Litigation Reform Act of 1995, as amended, indicating that certain statements contained in the slide presentation or in the press release are "forward-looking" rather than historical.

The Company undertakes no duty or obligation to update or revise information included in this Current Report or any of the Exhibits.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

The following exhibit is filed with this Current Report on Form 8-K:

Exhibit Number	Description
99.1	Press Release of Heat Biologics, Inc. dated February 28, 2019
99.2	Heat Biologics, Inc. Investor Presentation

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: February 28, 2019 HEAT BIOLOGICS, INC.

By:	/s/ Jeffrey Wolf
Name:	Jeffrey Wolf
Title:	Chairman, President and Chief Executive Officer

EXHIBIT INDEX

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